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MidTerm Overall Evaluation Report



PROPOSAL: 2000000076

TITLE: Robotic and Virtual Slide Telepathology

ACCOMPLISHMENTS

To date, we have reviewed several frozen section (FS) pathology cases in a retrospective fashion with remote, robotic real-time telepathology (TP). The telepathologist is given the usual clinical information with regard to organ site, sex and age of the patient and any pertinent clinical/radiographic information that was available on the surgical pathology tissue examination request form at the time of the intraoperative consultation. Each case is evaluated by TP without prior knowledge of the FS or final diagnosis and could be given a diagnosis or deferred if image/technical quality is sub-optimal. All slides used in the TP evaluation are later reviewed by conventional light microscopy by the same pathologist to assess intraobserver agreement between the TP and FS diagnosis. Later, all diagnoses are compared with the original FS and final diagnosis to assess interobserver agreement. Diagnostic errors were classified as interpretation errors if differences between TP and FS diagnosis are obtained, and as sampling errors, if discrepancies between the FS slides and slides prepared from formalin-fixed, paraffin-embedded tissues are seen. Agreements between the telepathology and glass slide diagnosis were reviewed and compared with the final diagnosis in conjunction with routine monthly intradepartmental quality assurance programs (new FS diagnosis versus final diagnosis). The Trestle Corporation (Newport Beach, CA) MedMicroscopy system has been initially installed at three referring institutions throughout the AMEDD. Initial installation sites include Walter Reed Army Medical Center (Washington, DC), Ireland Army Community Hospital (Fort Knox, Kentucky), Womack Army Medical Center (Fort Bragg, North Carolina) and Landstuhl Regional Medical Center (Landstuhl, Germany). Cases are transmitted from the daily workload. The use of consecutive cases eliminated bias related to case complexity. The remote consultation was not carried out as part of the intraoperative consultation or permanent section final diagnosis. The consulting pathologists at WRAMC, HAH and AFIP are blinded as to the diagnosis at the host site. The primary objective of this study is to compare the diagnostic accuracy of TP and FS diagnosis with conventional microscopy. The primary outcome variable in this study is the coded diagnosis. For each diagnostic session the TP diagnosis was recorded along with the time to diagnosis (TTD). This diagnosis is later compared with the FS diagnosis upon evaluation of the glass slide(s) used for the TP session. On-site training was provided by the vendor in conjunction with the project manager for this study from the WRAMC Department of Telemedicine and the pathologists at all the host and remote sites. A number of cases have been accrued into the study that represent several organ systems reflective of the surgical pathology workload within the AMEDD. 75% of the cases to date were for primary diagnosis (unknown disease process). The remaining 25% were FSs for staging procedures or extent of resection. Diagnostic concordance was determined by having similar coded text diagnoses with identical clinical significance. The diagnostic agreement between the TP and FS diagnoses was 100% (CI: 97.5-100%). No diagnoses were deferred pending glass slides based on specimen sampling/adequate numbers of slides or the technical quality of the telepathology system. The overall median TTD was 2'50" (0'50"- 9'00" minutes). Other qualitative data included the suitability of the image quality and overall technical performance. The image quality was rated as "4" or "excellent" in 98% of the cases with excellent cytologic and nuclear detail. The remaining two cases were rated "3" ("good") and "2" ("fair"). The overall technical quality of the system was rated as "4" ("excellent") in 97% of the cases.

PI's Accomplishment Evaluation: : Project Accomplishments Match Proposal

PROBLEMS

In cooperation with the vendor and the project manager from the WRAMC Department of Telemedicine, all 4 robotic microscopes and accompanying PCs have been successfully installed and networked to successfully transmit cases with standard internet connections that are preexisting in the AMEDD domains. Delays have been encountered with specific site network security issues that required support and close interaction with the Defense Information Systems Agency to insure network reliability. To date, the telepathology systems at Fort Knox, Fort Bragg, Landstuhl and WRAMC can be controlled remotely from any PC equipped with the viewer software and known IP addresses. Upon completing installation at Fort Knox, specific hospital and base network security issues were identified and configured to allow access to remote users. The following installations were done after these corrections were made to insure connectivity that was previously identified as being an issue at Ireland Army Community Hospital at Fort Knox. Since that time protocols have been put in place to identify specific hospital and base requirements as it pertains to use of the telepathology systems for remote access. Upon installation of the other sites to include Womack Army Medical Center, Fort Bragg, NC and Landstuhl Regional Medical Center, Landstuhl, Germany connectivity was complete with full remote access from Walter Reed Army Medical Center and the AFIP without difficulty. This was completed based on our experience with Fort Knox and specific Defense Information Systems Agency requirements outside of those specific for the hospital or base operations.

PI's Problem Area Evaluation: : *1. The system and its function are working well.*

LIFE-CYCLE

Plans for the project are the same goals as those addressed above. Telepathology is the practice of digitizing histological or macroscopic images for transmission along telecommunication pathways for diagnosis, consultation or continuing medical education. Previous studies have addressed static vs. dynamic imaging in several specimen types with a wide variety of systems and communication pathways. The goal of this project is to assess the validity of a web-based telepathology system for frozen section (FS) consultation within the Army Medical Department (AMEDD). The system provides real-time, dynamic remote control of a robotic microscope over standard Internet connections. Often times a solo-pathologist is called upon to provide diagnostic services without the support of immediate second/expert consultation during an intraoperative consultation. The use of telepathology (TP) is attractive because it provides an opportunity for pathologists to obtain immediate consultation. For purposes of the study, consecutive frozen section cases are diagnosed at a distance using the system. Intraobserver agreement between the TP diagnosis and glass slide (FS) diagnosis is observed. Diagnostic agreement to date is 100% for a wide variety of specimens. The preliminary data in this study suggests that such a system will help support pathologists located at distant sites. One of the most promising applications of telepathology is intraoperative consultation (frozen section diagnosis) to be allowed between small hospitals with pathology support located elsewhere, allowing operations requiring an intraoperative histopathological diagnosis pathology support without a pathologist on-site. Telepathology can also be used to support an isolated pathologist for second/expert consultation. Robotic telepathology for frozen section analysis and diagnosis should enable remote sites without direct pathologic support to obtain needed expert consultation, intraoperatively, thereby preventing medical errors, reducing costs, increasing quality and access to military personnel and their families. In the worldwide MHCS, continued physician downsizing is mandating a shift from medical support specialties. It is becoming increasingly necessary to employ technology to utilize these laboratory medicine specialists more effectively. No longer can the economies of scale support a single pathologist at small Army community hospitals. The loss of a pathologist means a sharp curtailment in the extent of surgical services that can be rendered at these community-sized hospitals. The request for consultation to an outside source is a standard procedure in surgical pathology practice. In particular, members of small pathology departments suffer from lack of "next door" specialists and consequently have a greater need to submit histological slides to a "remote" pathologist. Increasing documentation between countries is necessary to ensure the lack of biological risk associated with the submitted material. The use of remote pathology may allow full surgical pathology support to remote centers by pathologists located at distant sites. A validated remote pathology system, which meets community standards of diagnostic accuracy, will help support the current number of pathologists, while maintaining microscopic diagnostic support to community-sized hospitals & regional medical centers. Telepathology would enable full-time coverage, and it would reduce the travel time of the pathologist, which is expensive, non-productive professional time. This study is evaluating the feasibility and effectiveness of transmitting frozen section (intraoperative) slide images from a remote site to Walter Reed Army Medical Center (WRAMC) Department of Pathology, Heidelberg Army Hospital Department of Pathology or the AFIP. This is the first time any pathology project of this nature is being performed in the Army Medical Department (AMEDD).

PI's Life-Cycle Evaluation: : Project encountered no significant problems/issues

DELIVERABLES

Deliverable is on schedule, per Proposal as accepted with publication in progress as summarized below: Telepathology (TP) is the practice of digitizing histological or macroscopic images for transmission along telecommunication pathways for diagnosis, consultation or continuing medical education. Previous studies have addressed static vs. dynamic imaging in several specimen types with a wide variety of systems and communication pathways. The goal of this paper was to assess the validity of a web-based telepathology system for frozen section (FS) consultation within the Army Medical Department (AMEDD). The system provides real-time, dynamic remote control of a robotic microscope over standard Internet connections. Often times a solo-pathologist is called upon to provide diagnostic services without the support of immediate second/expert consultation during an intraoperative consultation. The use of telepathology (TP) is attractive because it provides an opportunity for pathologists to obtain immediate consultation. FS is technically limited and more difficult to interpret than examination of formalin-fixed, paraffin-embedded sections. Nevertheless, FS is regarded as an accurate means of diagnosis during surgery and often has a significant influence on the surgical operation being performed. The accuracy of FS diagnosis reported in the literature varies between 94% and 97.4%. Some of the results reported are combinations of different types of tissue submitted for FS, whereas others reflect specific tissue examined. For purposes of the study, consecutive frozen section cases are diagnosed at a distance using the system. Intraobserver agreement between the TP diagnosis and glass slide (FS) diagnosis was observed. Diagnostic agreement is 100% for a wide variety of specimens. The diagnostic agreement in our study to date is comparable to other rates of agreement (92-100% accuracy) in several recently published telepathology studies of FS, permanent section and cytological slides. Others have reported TP concordance for clinically important diagnoses compared with light microscopy by the same pathologist was achieved in 2138 of 2144 cases (99.7%). In a recent metaanalysis assessing the reliability of TP for frozen section service, a total of more than 1290 cases showed a slightly lower overall diagnostic accuracy of about 0.91 than the conventional FS with an average accuracy of about 0.99 found in an analysis of several studies of different organs. The difference is at least predominately caused by a higher rate of deferral and false negative FS diagnoses in the TP method, while the specificity of both methods, each more than 0.99 was not clinically different. Prospective studies on the diagnostic validity of telepathological FS diagnosis have previously been performed by several European, Scandinavian and Japanese investigators with a variety of telecommunication and telepathology systems. In the United States, investigators prospectively reviewed 99 intraoperative consultations from 29 tissue/organ sites. Statistical analysis indicated no significant difference between TP and conventional microscopy. In several recent studies, the use of telepathology for diagnostic purposes has been validated in the surgical pathology laboratory. Two international static TP consultative services have shown diagnostic accuracy rates of 88.2% and 100%, with an emphasize on the importance of the telepathologist to establish "diagnose vs. defer" decisions on consultation cases. Future studies will evaluate the effectiveness and feasibility for this technology to support real-time telepathology consultation between smaller hospitals, regional medical centers and the AFIP. In the future, clinically approved protocols will be developed for the provision of pathologic care using TP for routine, emergent, and FS diagnosis. This will support primary and second opinion pathology diagnosis throughout the worldwide MHCS.

PI's Deliverables Evaluation: : Deliverable is on schedule per Proposal

Expenditures

Element of Resource (EOR)	1ST Quarter Oct 1 - Dec 31	2nd Quarter Jan 1 - Mar 31
Travel 2100	\$0.00	\$2,586.00
Shipping 2200	\$0.00	\$0.00
Rent & Communications 2200	\$0.00	\$0.00
Contract for Services 2500	\$25,000.00	\$0.00
Supplies 2600	\$0.00	\$333.05
Equipment 3100	\$222,080.95	\$0.00

Financial Narrative:

Funds have been allocated as above.

PI's Financial Evaluation: : Deliverable is on schedule per Proposal

* END OF REPORT *